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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 17 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Transmittal of EFED re-registration documents for picloram products
(005101, 005102, 005103, 005104)

FROM: Ev Byington, Chief *Ev Byington*
Science, Analysis, and Coordination Staff
Environmental Fate and Effects Division

TO: Lois Rossi, Chief
Reregistration Branch
Special Review and Reregistration Division

Please find attached the following documents for the EFED re-registration review, for picloram products.

1. EFED Ecological Effects Branch (EEB) review (author Bill Evans).
2. EFED Environmental Fate and Effects Branch (EFGWB) review (author Kevin Poff).
3. Integrated EFED RED document.

Please note that the EEB document has attachments that are faxes from DowElanco, relating to application practices. These faxes will not be in electronic copies of any of the documents. Also note that the EEB and EFGWB documents contain extensive details not present in the integrated EFED document.

Four registered active ingredients are involved:

- 005101 Picloram Acid
- 005102 Picloram Triisopronolamine Salt
("TIPA", "TIPA Salt" or "Picloram TIPA Salt")
- 005103 Picloram Isooctyl Ester ("IOE" or "Picloram IOE")
- 005104 Picloram Potassium Salt ("Potassium Salt" or "Picloram Potassium Salt")

(In quotes are names of active ingredients generally used in this memo.)



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These chemicals are herbicides with terrestrial uses. There are no registered products containing the picloram acid, so environmental risks are assessed only for the other three active ingredients.

All four active ingredients are expected to be very similar in their biological and chemical characteristics in the environment: The acid and the two salts (TIPA and potassium) will actually become chemically identical in the environment, while IOE will degrade rapidly to the same form.

The available data for these chemicals are sufficient to indicate that *these chemicals are exceptionally hazardous to the environment. For many if not all picloram products and uses, the environmental risks cannot be effectively mitigated below a level of concern except by cancellation of registration.* The principal environmental risks that have been identified by the EFED are contamination of surface and groundwater, and damage to nontarget terrestrial plants including crops. There are additional concerns for risk to endangered terrestrial mammals and endangered aquatic animals.

Risks to nontarget organisms are assessed for each active ingredient. For a given active ingredient, the risk assessment is based on the maximum application rate for any products containing that active ingredient. Based on these application rates, nontarget plants in areas adjacent to areas of application may be exposed to chemical concentrations many times the levels for which toxic effects have been observed in laboratory studies. Numerous incidents of purported damage to crops have in fact been reported to the Agency, but full investigation of the merit of these reports would require data not presently available to the Agency. Application rates that would result in exposure concentrations below a level of concern for nontarget organisms vary with active ingredient and application procedure, but are uniformly below 1% of current application rates. Application procedures for picloram products are diverse, and the risk assessments do not consider all possible application procedures.

Picloram (in all of the forms considered) is among the most mobile of currently registered pesticides, and in some soils it is nearly recalcitrant to all degradation processes. Consequently, any continued use of picloram products will result in continued accumulation in groundwater in vulnerable areas. As of 1992, detections of picloram in ground water have been reported to the Agency for 10 states.

In the event that picloram is to be reregistered, there are data and labelling issues to be resolved. Regarding label modifications, eligibility for registration would require label restrictions on maximum annual application rates. These are missing from the labels of some active ingredients. These are missing from the labels for some products. (Because of inconsistencies in labelling, the EFED risk assessments for nontarget organisms have been based on the assumption of a single application.)

Various data requirements have not been fulfilled that would be needed for complete assessment of specific categories of environmental risk. These data include prospective groundwater monitoring, toxicity to aquatic plants, and toxicity to aquatic animals. For assessment of reports of incidents involving nontarget plants, the EFED would require

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confirmatory data for various crops. The value of the information that would be provided by completing the data requirements is arguably limited, because *available* data are sufficient to establish extreme risks.

Regarding any questions, please contact David Farrar (EFED/SACS) at 703-305-5721.

Notation: g ae = grams acid equivalent. Mass of anion for picloram acid, TIPA salt, and potassium salt.

cc Anne Barton
Hank Jacoby
Tony Maciorowski
Ev Byington
Elizabeth Loevey
Doug Urban
Akiva Abramovitch
Anne Stavola
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SACS File

MEMORANDUM

SUBJECT: Integrated EFED re-registration documents for picloram products
(005101,005102,005103,005104)

FROM: Ev Byington, Chief
Science, Analysis, and Coordination Staff
Environmental Fate and Effects Division

TO: Lois Rossi, Chief
Reregistration Branch
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Following is the EFED re-registration document for picloram products.

Four registered active ingredients are involved:

- 005101 Picloram Acid
- 005102 Picloram Triisopronolamine Salt
("TIPA", "TIPA Salt" or "Picloram TIPA Salt")
- 005103 Picloram Isooctyl Ester ("IOE" or "Picloram IOE")
- 005104 Picloram Potassium Salt ("Potassium Salt" or "Picloram Potassium Salt")

(In quotes are names generally used in the sequel.)

Regarding any questions, please contact David Farrar (EFED/SACS) at 703-305-5721.

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Use Profile

A. Environmental Assessment

-1. Environmental Fate

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3. Labelling Requirements and Potential for Mitigation

References 1. MRID Fate and Groundwater Studies

References 2. Other References

Use Profile

Of the four active ingredients evaluated, picloram acid is not an end use product. For the remaining three active ingredients, labels indicate maximum application rates of 2.2 lb ai/A per application for TIPA salt and 2.0 lb ai/A per application for both IOE and potassium salt. Labels for the most part do not specify minimum intervals between applications or other restrictions on annual application rates, so further label restrictions would be required for registration.

Picloram TIPA Salt. Five products are currently registered which contain mixtures of this TIPA salt with 2,4,D:

- Tordon RTU (5.4% TIPA, 20.9% 2,4,D)
Weed and Brush Control (EPA Reg. No. 62719-31)
(Control unwanted trees via cut surface treatment)
- Pathway (5.4% TIPA, 20.9% 2,4,D)
Vegetation Management (EPA Reg. No. 62719-31)
(Control unwanted trees via cut surface treatment)
- Tordon 101 mixture (10.2% TIPA, 39.6% 2,4,D)
Weed and Brush Killer (EPA Reg. No. 62719-5)
- Grazon P+D (10.2% TIPA, 39.6% 2,4,D)
Range and Pasture Management (EPA Reg. No. 62719-182)
- Tordon 101 R (5.4% TIPA, 20.9% 2,4,D)
Forestry Herbicide (EPA Reg. No. 62719-31 (formerly 464-510))
(Control unwanted trees via cut surface treatment)

The maximum application rate for TIPA salt is 2.2 lb ai/A per application, based on the label for Tordon 101 mixture applied by broadcast treatment of cut stubble (see table following).

It should be noted that the last three products essentially have the same registration number and differ only in the title of the use sites. The label wording for Tordon RTU and

Pathway are identical. These three pesticides are *not* restricted to use by certified applicators only. The products are used for the control of unwanted trees in forests, non-cropland areas such as fence rows, roadsides and rights-of-way and are applied by tree injection, frill or girdle treatment, or stump treatment. This treatment can be applied during any season and there are no label restrictions on the maximum number of treatments per season. The maximum rate per application is also unclear. For the tree injection method 1 ml of undiluted product is injected at intervals of 2 to 3 inches between the edges of injector wounds, however, it is not specified if 1 ml is injected at each interval or whether a total of 1 ml of product is injected per tree.

DowElanco was contacted on October 22, 1993 for clarification of application rates. Their reply indicates an application rate of 0.168 lb ai/A by the injection method. They further state that injection applications are "*typically applied*" once every 3 to 4 years at most (emphasis added).

Tordon 101 mixture and Grazon P+D are both Restricted Use Pesticides and can be applied by both aerial and ground equipment. Grazon P+D is registered for use in New Mexico, Oklahoma, Texas, Arkansas, Louisiana, Alabama, Georgia, and Mississippi only, and is applied to range and pasture at a maximum rate of 1 gallon/acre or 0.54 lbs ai/A (245 g/A) once a year. Tordon 101 mixture, has no restrictions on the maximum number of applications, and intervals between applications are also unrestricted. It is used

"for the control of unwanted annual and perennial broadleaved weeds and woody plants and vines on forest planting sites and non-crop areas including industrial manufacturing and storage sites, right-of-ways such as electrical power lines, communication lines, pipelines, highways, railroads, and wildlife openings in forest and non-crop areas".

The maximum application rate for single applications of Tordon 101 mixture varies with the type of target plant treated. These rates are summarized in the table below.

Maximum Application Rates per Application of Tordon 101 (Active Ingredient TIPA Salt)	
Targeted Plant Group	Maximum Single-Application Rate
Broadleaved Annual & Perennial Weed & Vines & Woody Plants	2 gal ai/A = 1.1 lbs ai/A = 499.4 g ae/A
Conifer Strip Thinning in the Northeast U.S.	3 gal ai/A = 1.6 lbs ai/A = 735.5 g ae/A
Broadcast Cut Stubble Treatment	4 gal ai/A = 2.2 lb ai/A = 980 g ae/A

Picloram IOE

The only registered product that contains IOE is "Access" (EPA Registration #464-576). That product is registered for application as a basal bark treatment, using backpack sprayers. (There are therefore no aerial application procedures for IOE, unlike potassium and TIPA salt.) Access contains IOE mixed with 32.5% Triclopyr. Application is by certified applicators only. Access can be applied during any season. The maximum number of treatments per season, or minimum intervals between treatments, are not addressed on the label.

Access is used "for control of unwanted woody plants in forests, rights-of-way such as electrical power lines, communication lines, pipelines, roadsides, and railroads, and on non-crop areas including industrial manufacturing and storage sites and fence rows."

Risk assessments for nontarget organisms are based on application of IOE at a rate of 2.00 lb ai/acre per application, based on application undiluted at 15 ml per stem, for 500 stems per acre. Access labels indicate the following rates and application procedures:

- Diluted as 2 gallons of product (908 g ae), in enough oil to make 100 gallons of spray mixture, and applied with a backpack sprayer, using low pressure (20 to 40 psi) at the spray nozzle.
- Diluted as 30 gallons (13,620 g ae) of product to make 100 gallons, and applied as a low volume treatment, using low pressure and a cone or flat fan nozzle.

(The only apparent difference between these two dilutions is that the low volume treatment does not wet the stem to the point of runoff.)

- Undiluted "in a thin stream to all sides of the lower stems". Between 2 to 15 ml (0.0005284 to 0.003969 g ae) is applied per stem.

DowElanco was contacted on November 3, 1993 for further clarification of maximum application rates, as for TIPA salt. They indicated that trees 1 to 6 inches in diameter require 5 to 30 milliliters per tree. The maximum density of target plants is said to be 500 stems per acre, which implies an application rate of 15,000 ml (3.96 gallons) per acre. As a 30% dilution 1.19 gallons of Access would be applied per acre. There is 1 lb ai/gallon, so the maximum application rate is 1.19 lb ai/A. Similarly, the 2% dilution represents an application rate of 0.24 lb ai/A.

The DowElanco communication did not directly address the undiluted application. Undiluted treatment of 15 ml per stem yields a maximum application rate of 2 lb ai/A (500 stems x 15 ml)/3785 ml/gallon) per application.

The Agency has not yet obtained data to verify the assumed maximum of 500 stems

treated per acre. The registrant has indicated verbally (March 1 "use" meeting) that the 500 stems/acre figure is a limit on stem density for which injection is economically viable.

Picloram Potassium Salt

The Picloram Potassium Salt is represented by three end use products as listed below.

- Tordon 22K (24.4% a.i.)
Small grain Control (EPA Reg. No. 62719-6)

- Tordon K (24.4% a.i.)
Industrial Rights-of-Way and Forestry Control
(EPA Reg. No. 62719-17)

- Grazon PC (24.4% a.i.)
Range and Pasture Control (EPA Reg. No. 62719-181)

All of the end-use products of this salt are Restricted Use Pesticides, and can be applied by both aerial and ground equipment. Grazon PC is registered for use in New Mexico, Oklahoma, and Texas only and is applied to range and permanent grass pasture at a maximum rate of 1 gallon/acre or 2 lbs ai/A (908 g/A) once a year, even though the label recommends not to use more than 1 quart/acre or 0.54 lb ai/A (227 g/A) for high-volume foliar applications. This product is used to control broadleaf annual and perennial weed, pricklypear, mesquite and other species, and can be applied employing both ground and aerial equipment.

Tordon K is used for control of unwanted annual and perennial broadleaved weeds, woody plants, and vines on non-crop areas including forest planting sites, industrial manufacturing and storage sites, right-of-ways such as electrical power lines, communication lines, pipelines, highways, railroads, and wildlife openings in forest. There are *no limitations on the maximum number of treatments per season*. Tordon K can be applied using several application methods including high-volume leaf/stem treatment, spot treatment, broadcast ground or aerial foliage treatment, and broadcast cut stubble treatment. The maximum single application rate is 2 quarts per acre or 1 lbs ai/A (454 g/A), except for the broadcast cut stubble treatment, for which the rate is 1 gallon/A, or 2 lbs ai/A (908 g/A).

Tordon 22K can be applied west of the Mississippi on rangeland and permanent grass pastures, fallow cropland, wheat, barley, oats, non-crop land (such as roadsides or other rights-of-way, along fence rows, and around farm building), on Conservation Reserve Program (CRP) and wildlife openings in forest. Treatments can be applied by aerial application or spot treatment. Although not specifically stated, it is inferred that Tordon 22K is applied one time per season with a maximum rate of 1 quart/A or 1/2 lb a.i./A (227 g/A) for broadcast applications and 1 gallon/A or 2 lb a.i./A (908 g/A) for spot treatments. Maximum broadcast and spot treatment rates are summarized in the table following for

various plant groups.

Label Use Restrictions for Tordon 22K (Active Ingredient Potassium Salt)	
Targeted Plant Group	Maximum Single-Application Rate (Broadcast and Spot Treatments)
Woody plants and Broadleaf Weeds	Broadcast rate: 1 quart ai/A = 1/2 lb ai/A = 227g ae/A Spot treatment rate: 1 gal ai/A = 2 lb ai/A = 908 g ae/A
Non-Cropland Areas such as rights-of-way, fence rows, and around farm buildings	Broadcast rate: 1/2 gal ai/A = 1 lb ai/A = 454 g ae/A
Rangeland and permanent Grass Pastures	Broadcast & Spot treatment rates: 1 quart ai/A = 1/2 lb ai/A = 227 g ae/A
Barley, Oats, and Wheat Not Underseeded With a Legume	Broadcast rate: 1 1/2 fl oz ai/A = 0.01 gal ai/A = 0.02 lb ai/A = 0.00004 g ae/A
Fallow Cropland (Not Rotated to Broadleaf Crops)	Broadcast rate: 1 pint ai/A = 1/4 lbs ai/A = 114 g ae/A Spot treatment rate: 1 gal ai/A = 2 lb ai/A = 908 g ae/A
Conservation Reserve Program (CRP) for Seeding to Permanent Grasses Only	Broadcast rate: 1 quart ai/A = 1/2 lb ai/A = 227 g ae/A Spot treatment: 1 gal ai/A = 2 lb ai/A = 908 g ae/A

A. Environmental Assessment

The principal environmental risks that have been identified by the EFED relate to contamination of surface and groundwater, and damage to nontarget terrestrial plants including crops, in areas adjacent to areas of application, via runoff or drift, and possibly from more distant areas where groundwater is used for irrigation or discharged into surface water. Nontarget plants, in areas adjacent to areas of application, may be exposed to chemical concentrations many times levels that have been associated with toxic effects. Numerous incidents of purported damage to crops have in fact been reported. In the case that this chemical is re-registered, more extensive investigation of these incidents is needed, along with more extensive hazard data for various crops. Additional concerns are identified relating to endangered terrestrial mammals and endangered aquatic animals.

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Picloram (in all of the forms considered) is *among the most mobile of currently registered pesticides, and in some soils it is nearly recalcitrant to all degradation processes. As of 1992, detections of picloram in ground water have been reported to the Agency for 10 states.*

Limitations of the quantitative ecological risk assessment include: a. Risk assessments are based on a single assumed application, because labels for the most part do not specify maximum annual rates. b. Risks are not assessed quantitatively for nontarget organisms exposed via irrigation with contaminated surface or ground water at sites distant from areas of application. Effects at distant locations are plausible in view of the high persistence, mobility, and phytotoxicity of these chemicals.

These chemicals are expected to be similar in their biological and chemical characteristics in the environment. For the three active ingredients excluding IOE, the part of the molecule that is principally responsible for biological activity is the anion, which is identical for all three active ingredients. For all three, the molecule will usually dissociate in the environment to yield free anions. Dissociation is governed by rate constants (pKa) that have practically the same value for all three active ingredients. IOE is expected to degrade fairly rapidly to the same anion (measured aerobic half-life 2 days).

As a consequence of this similarity, the different active ingredients are not usually distinguished in the ecological chemistry and fate review (Section 1), which refers to "picloram" or "the chemical" generically. The ecological effects review (Section 2) distinguishes among active ingredients on the basis of use profiles of registered products containing a given active ingredient. In particular, picloram acid is not used as an end product, and so the ecological risk assessment is limited to the salts (TIPA and potassium) and IOE.

Mitigation and Labelling. Because these chemicals are exceptionally mobile and persistent, *any continued use of picloram products will result in some continued accumulation in groundwater.*

The potential for mitigating effects on nontarget organisms *by use reduction* can be evaluated by estimating use rates for which environmental concentrations would not exceed levels of concern. For nontarget terrestrial plants, results of this calculation vary by active ingredient and application method, but are uniformly less than 1% of current rates.

Eligibility for registration would require label restrictions on maximum annual application rate that are not provided on some current labels, as indicated in the Use Profile section.

Data Requirements. Various data requirements have not been fulfilled that would be needed for a complete assessment of specific categories of environmental risk. For picloram

products, available data are sufficient to indicate that risks are extraordinary and cannot be mitigated below levels of concern without cancellation of registration.

The maximum contaminant level (MCL) for hexachlorobenzene has been set at 1 ppb.

1. Environmental Fate

a. Environmental Chemistry, Fate and Transport

In the following discussion, data requirements are first enumerated and categorized as: 1) satisfied, 2) not satisfied, 3) reserved, or 4) waived (Section (1)). Then a synthesis is presented based on studies found acceptable (Section (2)).

(1) Status of Data Requirements

Data requirements that have been satisfied.

161-1. Hydrolysis. IOE hydrolyses to picloram acid with a half-life of 61.5 days at pH 5, 38.7 days at pH 7, and 18.4 hours at pH 9 (Registration Standard, July 1988). Picloram (acid) is *stable* in both acidic and basic media (Registration Standard, July 1988).

161-2. Photodegradation in Water. Picloram (acid) in sterile buffered water as well as natural water degraded with a first order half-life of 2.6 days at 25°C. The two major photoproducts arising from picloram decomposition are oxamic acid and 3-oxo-Beta-alanine indicating dechlorination followed by subsequent cleavage of the pyridine ring to low molecular weight compounds. Oxamic acid reached a maximum of 32.90% at 96 hours and 45.47% at 120 hours in sterile buffered water and natural water respectively (MRID #164943, MRID #41092501).

Picloram-IOE degraded with a half-life (first order calculated) of 70.6 minutes in sterile aqueous buffered solutions (pH 5) irradiated with a Xenon light source at 25.1 to 26.0°C. The major photoproducts were an isomer of dichlorohydroxypicloram-IOE and isomers of dichloropicloram-IOE reaching a maximum of 24.6 and 15.0% at 120 minutes. Ion exclusion chromatography separated a polar mixture accounting for 32.3% of applied at 180 minutes into 3 components; one component was a mixture of carboxylic acids including oxamic acid (MRID #42811901)

161-3. Photodegradation on Soil. IOE degraded to picloram acid with a half-life of 115 days on sandy loam soil (MRID #41260101, 5/28/91). The registration standard (July 1988) gives supplemental data showing picloram (acid) to be *stable* to photodegradation on soil during 384 hours of irradiation; however, for that measurement the light spectrogram of the mercury arc sunlamp was not adequately compared to natural sunlight. The total intensity was 50 uW/cm² for 290-320 nm, the UV absorption maximum for picloram (Registration Standard, July 1988).

162-1. Aerobic Soil Metabolism. Picloram (acid) degraded in seven soils with half-lives ranging from 167-513 days. The major degradate was carbon dioxide (Registration Standard, July 1988).

IOE degraded with a half-life of <2 days in clay loam soil; Picloram (acid) accounted for 81.4% of applied at the studies conclusion (Registration Standard, July 1988).

162-2. Anaerobic Soil Metabolism. Picloram (acid) was *stable* to anaerobic degradation (picloram (acid) accounted for 89.3-92.2% of applied) after 300 days of incubation (Registration Standard July 1988).

162-3. Anaerobic Aquatic Metabolism. Picloram (acid) was *stable*, after 300 days of incubation 93.6-96.9% of applied was parent (Registration Standard July 1988).

162-4. Aerobic Aquatic Metabolism. *No data are required* because there are no registered aquatic uses (Registration Standard July 1988).

163-1. Leaching and Adsorption/Desorption. The Freundlich $K_{d(ads)}$ values for picloram (acid) were 0.98 for sandy loam, 0.31 for clay, 0.07 for sandy loam, 0.4 and 0.1 for sand. $K_{d(ads)}$ values for picloram (acid) ranged from 0.0-0.73 in sandy loam, loam, clay loam, and clay soils. (MRID # 00111473, supp. info. May 26, 1988). Further data from Racke, 1989: "An Adsorption/Desorption Study of Picloram" MRID #41209601 gave a mean Freundlich $K_{d(ads)}$ value of 0.5. Data for the acid may be used for IOE and potassium salt (see attached environmental equivalency argument).

164-1. Terrestrial Field Dissipation. In Davenport California at 1.6 lb picloram lbs ai/A dissipated from a bareground and short grass plot with half-lives (first order kinetics) of 278 and 135 days respectively (MRID #42579002).

In a study conducted in Alamance County, North Carolina, picloram applied at 2.0 lbs ai/A dissipated from a Colfax sandy loam bare soil (TBS) and short grass plot (TSG) with pseudo first order half-lives of 108 and 104 days respectively (MRID #42579001).

In a field dissipation study in Montana the average of 4 first-order dissipation values yielded a calculated half-life of 256 days with a standard deviation of 37 days (MRID #42535302, #42558302).

164-2. Aquatic (sediment) Dissipation. *No data are required* because there are no registered aquatic uses (Registration Standard July 1988).

164-3. Forestry. Picloram (Tordon K, potassium salt), applied aerially at 1.08 lbs ai/A (54% of maximum label rate) in Barnwell County, South Carolina dissipated with a calculated first order half-life of 123 ± 13 days (average of 3 subplots \pm bounds of 95% interval) in the exposed (bareground) soil and 34 ± 18 days in the unexposed (soil covered with leaf litter) soil (MRID #42579003).

In Ostrander, Washington the exposed (bare ground; picloram applied directly to soil) soil picloram half-life using a biexponential decay model was 5.3 days. The first order equation gave a half-life of 97.0 days. For unexposed soil (with vegetation and leaf litter cover), picloram half-life was estimated at 4.7 days using a biexponential decay model. The first order equation gave a half-life of 21.4 days (MRID #41395301).

165-3. Irrigated Crops. *No data are required* because there are no registered aquatic uses (Registration Standard July 1988).

165-4. Laboratory Accumulation in Fish. Picloram (acid) did not accumulate in bluegill sunfish. BCF factors were < 0.54 and < 0.17 in whole fish. The IOE also did not accumulate: BCF factors were 70 for whole fish, 8 for muscle, and 74 for remainder tissue (Registration Standard, July 1988).

Data requirements not satisfied.

166-1. Small-Scale Prospective Ground Water Monitoring. *All data are required.*

Based on the environmental fate characteristics and high phytotoxicity of picloram, the Agency requested in 1985 that the registrant conduct a small-scale retrospective ground water monitoring study. After completion of the Registration Standard, the request was converted to a small-scale *prospective* study. DowElanco responded by submitting a terrestrial field dissipation study conducted in Bremond, Texas (MRID #41646901, 8/27/91). That study was found by the Agency to be *unacceptable* as a substitute for the required study. Furthermore, the validity of the study submitted is questionable because the data were generated by Craven Laboratories. DowElanco later submitted data from two prospective monitoring studies (conducted in Montana and South Carolina), which had been begun and completed without Agency knowledge or input. The Agency found that these studies were inadequate to support the ground water monitoring requirement (MRID #42535302, #42558302, and #41395301).

The position of EFED is still an acceptable monitoring program would involve prospective monitoring.

201-1. Droplet size spectrum. *Required* as indicated in the 1988 Registration Standard, for products applied aerially (currently picloram TIPA and potassium salts).

202-2. Drift field evaluation. *Required* as indicated in the 1988 Registration Standard, for products applied aerially (currently picloram TIPA and potassium salts).

Registrants must submit (201-1) and (202-1) data for herbicides that are applied aerially and have high phytotoxicity. As indicated in Section 2 (Ecological Effects), all picloram active ingredients evaluated are very toxic to plants. DowElanco is a participant of the Spray Drift Task Force, and may submit 201-2 and 202-2 data in accordance with the appropriate

Pesticide Registration notice.

Data requirements reserved.

164-5. Long Term Terrestrial Field Dissipation (Registration Standard July 1988).

165-2. Rotational crop (field) (Registration Standard July 1988).

165-5. Accumulation in nontarget organisms (Registration Standard July 1988).

166-2. Small-Scale Retrospective Monitoring. (Registration Standard July 1988).

Data Requirements Waived.

161-2. Photolysis in Water, Potassium salt. The Agency agreed that there is no practical chemical or environmental difference between the picloram salt and acid (communication 5/29/90 from Edwin F. Tinsworth, USEPA, to Douglas Roby, DowElanco).

161-3. Photolysis in Soil, Potassium salt. The Agency agreed that there is no practical chemical or environmental difference between the picloram salt and acid (communication 5/29/90 from Edwin F. Tinsworth, USEPA, to Douglas Roby, DowElanco).

161-4. Photolysis in air. Based on the Registration Standard (July 1988), no data are required for the salts because of relatively low vapor pressure. No data are required for IOE because there are no terrestrial food uses.

162-3. Anaerobic Aquatic Metabolism. Waiver granted on 6/19/89 for IOE.

163-1. Leaching/Absorption/Desorption, Potassium salt. The Agency agreed that there is not chemical/environmental difference between the picloram salt and acid (communication 5/29/90 from Edwin F. Tinsworth, USEPA, to Douglas Roby, DowElanco).

163-2. Volatility (lab). Waived based on Registration Standard, as described for 161-4.

163-3. Volatility (field). Waived based on Registration Standard, as described for 161-4.

(2) Technical Discussion

The four active ingredients are expected to have very similar fate and transport characteristics in the environment. For the three excluding IOE, the part of the molecule that is principally responsible for biological activity is the anion, which is chemically identical for all three active ingredients. For all three, the molecule will usually dissociate in the environment to yield free anions, and the dissociation process is governed by a rate constant (pKa) that is practically the same in value for all three: literature submitted by the

registrant indicates measured pKa approximately 2 for the acid and salts (Osteryoung and Wittaker, 1980; Reim, 1989; Woodburn et al. 1989; Skurlatov et al., 1983). IOE is expected to degrade rapidly (measured aerobic half-life 2 days), to forms with the same anion as the acid and the salts. Consequently, IOE is expected to have environmental fate characteristics very similar to those of the other active ingredients.

The acid and salts are highly soluble in water (> 100 ppm). The Picloram acid water solubility is 560 ppm, while that of the Potassium salt is 740,000 ppm at 20° C. From these values, it follows that at typical soil pH (5-9) the anionic form comprises greater than 99% of the dissolved chemical, regardless of the original molecular species. Therefore, regardless of the original molecular form, the physical/chemical properties of the anion may be used to predict the environmental fate of the applied molecule or formulation. IOE water solubility is considerably lower at 0.23 ppm at 20° C. However, again, IOE degrades quickly to the highly soluble anion.

Based on the high solubility of picloram in water, and on resistance to biotic and abiotic degradation processes, as well as the proven mobility of the chemical under both laboratory and field conditions, it appears that the major route of dissipation for the chemical is leaching. Based on low vapor pressure of picloram, volatilization from soils will not be an important dissipation mechanism.

Picloram acid has a significant number of physical/chemical characteristics in common with various pesticides known to leach to ground water. Picloram acid has a water solubility of 560 ppm, and is anionic at the environmentally significant pH ranges. The chemical is relatively stable to hydrolysis at acidic and neutral pH's: [half-life is 61.5 days at pH 5 and 38.7 days at pH 7.] Data on aerobic soil metabolism show that picloram acid degrades with half-lives ranging from 167 to 513 days in seven soils, with carbon dioxide the major degradate. (Two minor degradates are 4-amino-3,5-dichloro-2-pyridinol and 4-amino-2,3,5-trichloro pyridine.) Data on anaerobic soil and anaerobic aquatic metabolism indicate that picloram acid is stable to anaerobic degradation, with over 90% of the chemical not degraded after 300 days of incubation. Soil photolysis data indicate that picloram acid is stable when irradiated on soil. Batch equilibrium studies of soils with varying cation exchange capacity indicate that the chemical will be very mobile (Freundlich $K_{d(ads)}$ values < 1), for soils with organic matter (OM) content as high as 4.2%.

No acceptable ground water monitoring studies have been submitted to the Agency; however, available soil residue studies clearly indicate that picloram has very high potential to leach into ground water in most soils and the chemical has been detected in 10 states to date (USEPA 1992; 734/12-92-001). For picloram that reaches surface waters through runoff there would be some degradation, as indicated by the aqueous photolysis study which showed a first-order half-life of 2.6 days for the acid, at 25°C.

Forestry and terrestrial field data available to the Agency indicate that picloram is extremely mobile under field conditions. In a forestry dissipation study conducted in South

Carolina, picloram applied at the maximum application rate of 2.0 lb ai/A (see Use Profile Section) was detectable 840 days after application, in the deepest samples (1.8 m). In study conducted in North Carolina, picloram applied at 2 lbs ai/A to a bare soil plot and short grass plot (both with 4.01% OM) was detected in all sampling intervals beyond 8 weeks, in the deepest soil samples (75 to 90 cm). In a field dissipation study conducted in Montana (MRID #42535302, 42558302), picloram applied at half the maximum label rate (i.e. at 1 lb ai/A) was detectable 790 days after application in the 48 to 60 inch soil layer (maximum sampling depth 72 inches; soil with 2.2% OM). In a forestry dissipation study conducted near Ostrander Washington, picloram applied at half the maximum label rate to exposed soil was detectable nine months after treatment in the deepest samples (36 inches). (Soil with 3.7% OM.)

Data recently submitted to the Agency by T.L. Lavy and colleagues (University of Arkansas) indicate that picloram leached but did not degrade over a three-year period in a Crevasse loamy fine sand treated at depths of 0 to 1.5 meters (data resulted from cooperative special project CR-815154-03-0). In fact, nearly 100% of the applied chemical leached from the treated soil over the first three years of the study, but none of the picloram degraded. In a Captina silt loam, picloram was mostly degraded within six months to one year, depending on soil depth. Given the high persistence of picloram in coarse-textured soils, it appears unlikely that picloram will degrade once it reaches ground water, even over a period of several years.

Supplemental laboratory studies by Watson et al. (1989) found that picloram was more persistent and mobile in a coarse-textured soil (sandy loam with 61% sand and about 1.4% organic matter) than in a finer textured soil (loam with 33% sand and about 3% organic matter).

Given the low octanol-water partition coefficient, significant bioaccumulation in aquatic organisms is not anticipated.

b. Environmental Fate Assessment

The MCL for picloram has been established at 500 ppb. Picloram is a Class D carcinogen. Picloram generally does not pose a threat to human health at the levels that have been detected in ground water to this date.

As described in greater detail in Section 2, concerns are related principally to effects on nontarget plants. Exposure to nontarget plants may occur via the following transport mechanisms.

- Exposure of terrestrial plants in areas adjacent to areas of application, by drift and/or runoff from areas of application. (Assessed quantitatively in Section 2).

- Exposure of crops by irrigation with contaminated surface or ground water. (As indicated in Section 2, incidents of crop damage have been reported, that would require further consideration in order for the chemicals to be re-registered.)
- Exposure of aquatic plants, via runoff or drift from application areas, and via discharge of contaminated ground water into surface water.

Ground Water. Data currently available to EPA indicate that picloram has been detected in ground water in 10 states at concentrations ranging up to 30 ppb. The following concerns have been identified:

- **high mobility and persistence.** Environmental fate data indicate that picloram is mobile and persistent in laboratory and field studies. Picloram (in all of the forms considered) is among the most mobile of the currently registered pesticides. In some soils it is nearly recalcitrant to all degradation processes.
- **ground water quality.** The *Pesticides in Ground Water Database* (USEPA 1992; 734/12-92-001) indicates that as of 1992, detections of picloram in ground water have been reported in Iowa, Kansas, Maine, Minnesota, Montana, North Dakota, South Dakota, Texas, Virginia, and Wyoming. Concentrations in ground water range up to 30 ppb. Picloram has been detected in a variety of environments in these states, although below the toxicity threshold for human health.

Considering the widespread use of picloram and the detections in many states, the Agency is concerned about degradation of water quality in picloram use areas. Despite a specialized use pattern, eventual contamination of ground water is virtually certain in areas where residues persist in the overlying soil. Once in ground water, the chemical is unlikely to degrade even over a period of several years.

Surface Water. Picloram has high potential to contaminate surface water by runoff or drift from use areas, and by discharge of ground water into surface water. The chemical has been detected in surface water at levels below the MCL. Picloram is not a standard analyte in most surface water monitoring studies.

2. Ecological Effects

a. Ecological Effects Data

The following acute and chronic studies have been reviewed and can be used in risk assessment for birds for the four active ingredients of Picloram.

(1) Non-target Terrestrial Animals

i. Birds

Picloram Acid

P.C. Code: 005101

GLN #	TEST TYPE	MRID #	EVALUATION DATE CLASSIF.	% A.I.	TEST DATE	RESUL T
71-1(a)	Mallard, Acute Oral LD ₅₀	Accession #'s 261883 265983 40054501 MRID # 157173	7/1/87 core	93.8	1983	LD ₅₀ > 2150 mg/kg

This avian study conducted with technical grade acid indicates that the technical grade of the active ingredient is practically nontoxic to birds on an acute oral basis (LD₅₀ > 2150 mg/kg). This was the only avian study conducted with the acid.

Picloram TIPA Salt

P.C. Code: 005102

GLN #	TEST TYPE	MRID #	EVALUATION DATE CLASSIF.	% A.I.	TEST DATE	RESUL T
71-2(a)	Quail, Dietary LC ₅₀	not listed	10/14/82 supplemental (not completed with TGAD)	10.2	1975	LC ₅₀ > 10,000 ppm
71-2(b)	Mallard, Dietary LC ₅₀	not listed	10/14/82 supplemental (not completed with TGAD)	10.2	1975	LC ₅₀ > 10,000 ppm

71-4(a) (Not required)	Ring-neck pheasant, Avian Reproduction	not listed	10/14/82	supplemental (not completed with TGAI or correct test species)	10.2	1974	NOEC = 2.8 kg/ha
71-4(a) (Not required)	Chicken, Avian Reproduction	not listed	10/14/82	supplemental (not completed with TGAI or correct test species)	10.2	1974	NOEC = 2.8 kg/ha

The avian dietary studies conducted with a product with 10.2 % of technical grade active ingredient indicate that the test material is practically nontoxic to birds on an acute dietary basis ($LC_{50} > 5620$). Additionally, two reproduction studies put NOECs at 2.8 kg/ha.

Picloram IOE

P.C. Code: 005103

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
71-2(a)	Quail, Dietary LC_{50}	Accession #'s 265982	6/29/87	core	100	1986	$LC_{50} > 5620$ ppm
71-2(a)	Quail, Dietary LC_{50}	164726	5/5/88	core	Tech. (% not given)	1986	$LC_{50} > 5620$ ppm

The avian dietary studies conducted with technical grade active ingredient indicate that IOE is practically nontoxic to birds on an acute dietary basis ($LC_{50} > 5620$).

Picloram Potassium Salt

P.C. Code: 005104

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
71-1(a)	Mallard, Acute Oral LD_{50}	164726	5/20/88	core	tech. (% not given)	1985	$LD_{50} > 2250$ mg/kg
71-1(a)	Quail, Acute Oral LD_{50}	164727	5/20/88	core	tech. (% not given)	1985	$LD_{50} > 2250$ mg/kg
71-2(a)	Quail, Dietary LC_{50}	REOPIC 08	10/14/82	supplemental because study was not conducted with TGAI	11.6	1975	$LC_{50} > 10,000$ ppm

71-2(a)	Mallard, Dietary LC ₅₀	REOPIC 07	10/14/82	supplemental because study was not conducted with TGAI	11.6	1975	LC ₅₀ > 10,000 ppm
71-2(a)	Mallard, Dietary LC ₅₀	129070	10/14/82	supplemental because study was not conducted with TGAI	24.4	1975	LC ₅₀ > 10,000 ppm
71-2(a)	Quail, Dietary LC ₅₀	129068	10/14/82	supplemental because study was not conducted with TGAI	24.4	1975	LC ₅₀ > 10,000 ppm
71-2(a)	Quail, Dietary LC ₅₀	Accession #'s 261883 265983 40054501	7/1/87	core	38.6	1982	LC ₅₀ > 5620 ppm
71-4(a) (not required)	Chicken, Avian Reproduction	not given	10/14/82	supplemental was not conducted with TGAI and required species was not used	24.4	1978	NOEL = 11.2 kg/ha

The two avian acute oral studies conducted with technical grade active ingredient imply that Picloram Potassium Salt is practically nontoxic on an acute oral basis (LD₅₀ > 2150 mg/kg). Testing on a products containing 11.2, 24.4, and 38.6% of technical grade active ingredient indicate that this salt is practically nontoxic on an acute dietary basis (LC₅₀ > 5620). An avian chicken study revealed a NOEC of 11.2 kg/ha for reproductive effects.

ii. Mammals

Essential results, by active ingredient are:

- Picloram acid, the parent compound, is practically nontoxic to mammals based on an acute oral rat LD₅₀ > 5000 mg/kg for males and a LD₅₀ = 4012 mg/kg for females. Acute inhalation LC₅₀ > 0.035 mg/l for both sexes.
- The TIPA salt tested with 33.9% a.i. is practically nontoxic to mammals based on an acute oral rate LD₅₀ > 5000 mg/kg for males and females. The LC₅₀ for an acute inhalation is > 0.07 mg/l.
- IOE is practically nontoxic to mammals based on an acute oral rate LD₅₀ = 2830 mg/kg for males and LD₅₀ = 3250 mg/kg for females.
- The Picloram Potassium Salt TIPA salt tested with 38.8% a.i. is practically nontoxic to mammals based on an acute oral rate LD₅₀ > 5000 mg/kg for males and a LD₅₀ = 3536 mg/kg for females. The LC₅₀ for an acute inhalation is > 1.63 mg/l.

(2) Non-target Aquatic Animals

i. Freshwater Animals

The following table summarizes the acute and chronic data which can be used in risk assessment for freshwater organisms for the four active ingredients of Picloram.

Picloram Acid
P.C. Code: 005101

GLN #	TEST TYPE	MRID	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
72-1(a)	Bluegill, Acute LC ₅₀	00129078	10/15/82	core	92.74	1978	LC ₅₀ = 19.4 mg/l
72-1(a)	Bluegill, Acute LC ₅₀	112016	10/14/82	core	92.9	1974	LC ₅₀ = 14.5 mg/l
72-1(c)	Rainbow, Acute LC ₅₀	112016	10/14/82	core	92.9	1974	LC ₅₀ = 5.50 mg/l
72-2(a)	Daphnia, Acute LC ₅₀	0096-008	12/21/88	core	90	1977	LC ₅₀ = 34.4 mg/l
72-6	Aquatic Org. Accum. (Bluegill)	1218947 (access. no.)	7/29/82	core, but was classified as supplemental because it was never required for registration	99.6	1980	< 1 (Won't accum. in aquatic organisms)
72-6	Aquatic Org. Accum. (Channel Catfish)	none listed	10/14/82	core, but was classified as supplemental because it was never required for registration	99.6	1980	< 1 (Won't accum. in aquatic organisms)
N.A.	Field runoff conditions for cutthroat trout	129085	12/6/82	Supplemental because it was never required for registration	90	1979	Study concludes that conc. as low as 610 µg/l will affect survival & growth.
N.A.	Field runoff conditions for cutthroat trout	REOPICO2	10/14/82	supplemental because it was never required for registration	90	1979	Study concludes that conc. as low as 290 µg/l will affect survival & growth.

The above table characterizes the Picloram acid as moderately toxic to freshwater fish with a LC₅₀ of 5.5 mg/l (ppm) and slightly toxic to freshwater invertebrates (LC₅₀ of 34.4

mg/l). Field runoff studies conducted with cutthroat trout concludes that concentrations as low as 290 $\mu\text{g/l}$ and 610 $\mu\text{g/l}$ will affect survival & growth of cutthroat trout. Because of unforeseen difficulties, the reviews of these studies will need to be repeated. Therefore conclusions of an NOEC or LOEC as low as 290 $\mu\text{g/l}$ cannot be confirmed at this time

There are no records indicating that tests for freshwater invertebrates (*Daphnia magna*) have been conducted. The acid is not used as an end product, so this test is not required.

Picloram TIPA Salt
P.C. Code: 005102

GLN #	TEST TYPE	MRID	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
72-1(c)	Rainbow, Acute LC ₅₀	not listed	10/14/82	supplemental	98-99	1968	LC ₅₀ = 375 mg/l
72-1(d)	Rainbow, Acute LC ₅₀ - TEP	not listed	10/29/82	supplemental	8.1	1968	LC ₅₀ = 25 mg/l
72-1(d)	Rainbow, Acute LC ₅₀ - TEP	not listed	10/29/82	supplemental	2.5	1968	LC ₅₀ = 1250 mg/l
No guideline requirement	Coho salmon, Acute LC ₅₀	not listed	10/29/82	supplemental	10.2	1979	LC ₅₀ = 20 mg/l

The above table characterizes this Picloram salt as slightly toxic to freshwater fish with a LC₅₀ of 25 mg/l (ppm). However, a test with coho salmon yielded a LC₅₀ of 20 ppm. There are no records indicating that tests have been conducted with freshwater invertebrates; therefore a test using *Daphnia magna* is a standard requirement.

Picloram IOE
P.C. Code: 005103

There is no data for freshwater organisms for IOE. At a minimum the EFED will require the acute LC₅₀s for a coldwater fish (rainbow trout), a warmwater fish (Bluegill), and a freshwater invertebrate (*Daphnia magna*).

Picloram Potassium Salt
P.C. Code: 005104

GLN #	TEST TYPE	MRID	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
72-1(a)	Bluegill, Acute LC ₅₀	GS0096-007	10/29/82	supplemental due to lack of raw data	91	1966	LC ₅₀ = 24 mg/l
72-1(c)	Rainbow, Acute LC ₅₀	GS0096-007	10/29/82	supplemental due to lack of raw data	91	1966	LC ₅₀ = 13 mg/l
72-1(d)	Rainbow, Acute LC ₅₀	Not given	10/14/82	core for formulated product only	24.4	1977	LC ₅₀ = 26 mg/l
72-2(a)	Daphnia, Acute LC ₅₀	151783	5/20/85	core	93.8	1984	LC ₅₀ = 68.3 mg/l
72-2(b)	Daphnia, Acute LC ₅₀ (TEP)	Not given	10/14/82	supplemental (not conducted with TGAD)	88.6	1977	LC ₅₀ = 226 mg/l
72-4(a)	Rainbow Trout, Early life Stage	151784	2/12/85	core	93.8	1984	LOEC = 0.88 mg/l NOEC = 0.55 mg/l MATC = 0.70 mg/l
72-4(b)	Life-Cycle Aquatic Invertebrate	151783	5/20/85	core	93.8	1984	MATC = 14.6 mg/l NOEC = 11.8 mg/l LOEC = 18.1 mg/l

The above table characterizes this Picloram Potassium salt as moderately toxic to freshwater fish with a LC₅₀ of 13 mg/l (ppm) and slightly toxic to freshwater invertebrates (LC₅₀ of 68.3 mg/l). The fish early life stage and the Life-Cycle Aquatic Invertebrate Studies gave LOECs of 0.88 mg/l and 18.1 mg/l respectively as indicated.

ii. Toxicity to Marine and Estuarine Organisms

As the use of products containing picloram may be expected to enter a marine/estuarine environment a limited amount of data which can be used in risk assessment for marine/estuarine organisms is required. The data presently reviewed for the marine/estuarine studies are presented below.

Picloram Acid
P.C. Code: 005101

There is no marine/estuarine data for the parent compound Picloram acid. As no products containing the acid are used for anything other than manufacturing use product, no data requirements are required at this time.

Picloram TIPA Salt
P.C. Code: 005102

GLN #	TEST TYPE	MRID	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
72-3(e)	Oyster, Shell deposition EC ₅₀	not listed	10/14/82	supplemental (not tested with TGAD)	10.3	1975	10 < EC ₅₀ < 18 ppm
72-3(f)	Shrimp, Acute EC ₅₀	not listed	10/14/82	supplemental (not tested with TGAD)	10.3	1975	EC ₅₀ = 306 ppm

The above table characterizes this Picloram salt as slightly toxic to marine/estuarine mollusc with an EC₅₀ between 10 and 18 mg/l (ppm) and practically nontoxic to marine crustaceans (EC₅₀ = 306 ppm). As this salt is lacking data on marine/estuarine fish, an acute marine/estuarine fish study will be required.

Picloram IOE
P.C. Code: 005103

There is no data for marine/estuarine or freshwater organisms for IOE. As the use of products containing picloram may be expected to enter a marine/estuarine environment a limited amount of data which can be used in risk assessment for marine/estuarine organisms is required. At a minimum the EFED will require the acute LC/EC₅₀s for marine/ fish, mollusc, shrimp studies.

Picloram Potassium Salt
P.C. Code: 005104

GLN #	TEST TYPE	MRID	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
72-3(e)	Oyster, 48-h Embryo Larvae EC ₅₀	111560	10/14/82	core for formulated product only	11.6	1975	EC ₅₀ > 1000 ppm
72-3(e)	Oyster, 48-h Embryo Larvae EC ₅₀	129073	10/14/82	core for formulated product only	24.9	1975	18 ppm < EC ₅₀ < 32 ppm

The above table also characterizes this Picloram salt as slightly toxic to marine/estuarine mollusks and invertebrates with an EC₅₀ between 18 and 32 mg/l (ppm). As with the TIPA salt this salt is lacking data on marine/estuarine fish, an acute marine fish study will be required.

(3) Non-target Insects

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Data from a honey bee acute toxicity studies for all a.i.'s of picloram including the acid, IOE, and the two salts indicate that Picloram is practically nontoxic to honey bees with the lowest contact LD₅₀ > 25 micrograms per bee for the IOE. The data is summarized in the tables below.

Picloram Acid
P.C. Code: 005101

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
141-1	Honey Bee LC ₅₀ Study	None	10/29/82	supplemental; test conducted with a mixture	8.7 as mixture	1965	LC ₅₀ > 1000 ppm
No required guideline	Honeybee LC ₅₀	Not given	12/14/82	supplemental (not required guideline requirement)	Aqueous emulsion (% not given)	1965	LC ₅₀ > 4,000 ppm
No required guideline	Honeybee LC ₅₀	129066	10/29/82	supplemental (not required guideline requirement)	Aqueous emulsion (% not given)	1965	LC ₅₀ > 500 ppm
No required guideline	Honey Bee LC ₅₀	None given	12/14/82	supplemental (not a required guideline requirement)	18.1 as mixture	1972	No significant mortality above controls at 4 lb a.i./ acre

Picloram TIPA Salt
P.C. Code: 005102

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
141-1	Honey Bee Acute Contact Study	413669-01	4/90/92	core	5.68	1989	LD ₅₀ > 100 µg/bee
No required guideline	Honeybee LC ₅₀	No given	10/29/82	supplemental	8.7	1965	LC ₅₀ > 1000 ppm
No required guideline	Honeybee Tox. study	none cited	6/30/82	supplemental	18.1	1972	LC ₅₀ ≤ controls

Picloram IOE
P.C. Code: 005103

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	YEAR	RESULT
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141-1	Honey Bee Acute Contact Study	421211-07	1/4/93	core	89.7	1991	LD ₅₀ > 25 µg/bee
141-1	Honey Bee Acute Contact Study	426259-01	6/3/93	core	4.7 as mixture	1992	LD ₅₀ > 25 µg/bee

Picloram Potassium Salt
P.C. Code: 005104

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	YEA R	RESULT
141-1	Honey Bee Acute Contact Study	413669-02	4/92	core	35.2	1989	LD ₅₀ > 100 µg/bee
No required guideline	Honeybee LC ₅₀	Not given	12/14/82	supplemental because test not conducted with TGAI	23.6	1965	LC ₅₀ > 5,000 ppm
No required guideline	Honeybee LC ₅₀	Not given	10/29/82	supplemental because test not conducted with TGAI	8.7	1965	LC ₅₀ > 500 ppm
No required guideline	Honeybee Tox study	not given	6/30/82	supplemental because test not conducted with TGAI	24.4	1972	No significant mortality above controls at 4 lb a.i./ acre

(4) Non-target Plants (Terrestrial, Aquatic)

Generally, nontarget plant data are required only for herbicides and fungicides, but may be required for any pesticide if phytotoxicity concerns cannot be resolved from the open literature or existing Agency data bases. Testing can be accomplished at the Tier 1 and/or Tier 2 level. Before the implementation of the current policy paper ("the White Paper" or "New Paradigm") resulting from the Ecological Fate and Effects Task Force, the Agency could request Tier 3 field studies when the Estimated Environmental Concentration (EEC) exceeds the EC₂₅ for terrestrial plants or the EC₅₀ for aquatic plants. At present, Tier 3 plant studies fall under the current paradigm and Tier 3 studies are no longer requested, but the criteria noted for mitigation purposes. The Tier 1 level tests are carried out at the maximum label rate, and if more than 50% adverse effects are noted for aquatic plants and 25% adverse effects for terrestrial plants, Tier 2 testing will be required. Tier 2 tests use multiple dosages to determine an EC₅₀ or EC₂₅ and a NOEC for the plant species tested in Tier 1. Nontarget Phytotoxicity data is required automatically at the Tier 2 level for all herbicides applied aerially, via mist blowers, and with most irrigation equipment. In many cases Tier 1 tests are bi-passed and the registrant begins with Tier 2 tests. The current data base is presented in the tables below. Please note that a number of test species are missing for Tier 2 guidelines.

Picloram Acid
P.C. Code: 005101

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
122-1(b)	Vegetative Vigor Tier 1	261128 (accession no.)	4/29/86	supplemental (needs to be repeated or go to Tier 2)	not given	1985	No valid results
122-2	Aquatic plant Tier 1	261128 (accession no)	4/29/86	core for <u>S. Capricornutum</u>	93.4	1986	EC ₅₀ = 36.9mg/l
122-2	Aquatic plant - freshwater & saltwater species (<u>Euglena gracilis</u> & <u>Pedisastrum sp.</u>)	none listed	10/29/82	supplemental	91	1970	NOEC < 24 mg/l

Picloram TIPA Salt
P.C. Code: 005102

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
122-2	Aquatic plant - freshwater & saltwater species (<u>Euglena gracilis</u> & <u>Pedisastrum sp.</u>)	none listed	10/29/82	supplemental	91	1970	NOEC < 24 mg/l
123-1(a)	Seed Germination /Seedling Emerg. - Tier 2	412965-01	5/25/93	supplemental (NOECs lacking for soybean and EC ₂₅ missing for barley)	6.094	1989	Seed Germ. Soybean EC ₂₅ = 23 & NOEC < 0.25 g ac/ha Barley EC ₂₅ > 70 & NOEC = 35 g ac/ha Seed Emerg. Soybean EC ₂₅ = 0.027 & NOEC < 0.081 g ac/ha Wheat EC ₂₅ = 38.8 & NOEC = 17.5 g ac/ha

123-1(b)	Vegetative Vigor - Tier 2	412965-01	5/25/93	supplemental (NOECs lacking for soybean & tomato)	6.094	1989	Tomato EC ₂₅ = 0.22 & NOEC < 0.125 g ac/ha Wheat EC ₂₅ = 227.7 & NOEC = 70 g ac/ha
123-2	Growth & Reproduction of Aquatic Plants - Tier 2	414077-01	5/26/93	core for <u>S. capricornutum</u> only	5.7	1990	EC ₅₀ = 234 mg/l NOEC = 18.5 mg/l

Picloram IOE

P.C. Code: 005103

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
123-1(a)	Seed Germination/ Seedling Emerg. - Tier 2	412965-01	5/25/93	supplemental (NOEC lacking for drybean)	11.7	1989	<u>Seed Germ.</u> Drybean EC ₂₅ = 15 & NOEC < 0.25 g ac/ha Barley EC ₂₅ = 3.6 & NOEC = 1.1 <u>Seed Emerg.</u> Drybean EC ₂₅ = 0.004 & NOEC < 0.081 g ac/ha Wheat EC ₂₅ = 28.4 & NOEC = 8.8 g ac/ha
123-1(b)	Vegetative Vigor - Tier 2	412965-01	5/25/93	supplemental (NOECs lacking for soybean)	11.7	1989	Soybean EC ₂₅ = 0.24 & NOEC < 0.125 g ac/ha Wheat EC ₂₅ = 235.3 & NOEC = 70 g ac/ha
123-2	Growth and Reproduction of Aquatic Plants - Tier 2	426459-01	6/15/93	core for <u>S. capricornutum</u> only	4.7 as mixture	1993	EC ₅₀ = 4.9 mg/l NOEC = 3.2 mg/l LOEC = 5.5 mg/l

Picloram Potassium Salt

P.C. Code: 005104

GLN #	TEST TYPE	MRID #	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
122-1(b)	Vegetative Vigor Tier 1	261128 (accession no.) (Hemphill, D.D.)	4/29/86	supplemental (needs raw data or go to Tier 2)	not given for Tordon 22K	1986	Info. in summary form. Need raw data.
123-2	Growth and Reproduction of Aquatic Plants - Tier 2	414077-02	5/26/93	core for <u>S. Capricornutum</u> only	35.2	1990	EC ₂₅ = 52.6 mg/l NOEC = 13.1 mg/l
0124-2	Terrestrial Field Study - Tier 3 (modified)	Acc. # 261128 (Herr, Stroube, Ray)	4/29/93	supplemental, can't be up-graded; many deviations from protocol	not given for Tordon product	1986	Cannot be accessed due to insuff. no. plant spp.
124-2	Terrestrial Field Study - Tier 3 (modified)	Acc. # 261128	4/29/93	supplemental, can't be up-graded; many deviations from protocol	21.5	1986	Cannot be accessed due to insuff. no. plant spp.
124-2	Terrestrial Field Study - Tier 3 (modified)	Acc. # 261128	4/29/86	supplemental, can't be up-graded; many deviations from protocol	not given	1986	Cannot be accessed due to insuff. no. plant spp.
123-1(a)	Seed Germination/ Seedling Emerg. - Tier 2	412965-01	5/25/93	supplemental (lacks NOECs for soybean & drybean and lacks EC ₂₅ for barley)	0.2885	1989	<u>Seed Germ.</u> Soybean EC ₂₅ = 35 & NOEC = 0.25 g ae/ha Barley EC ₂₅ > 70 & NOEC = 4.4 g ae/ha <u>Seed Emerg.</u> Soybean EC ₂₅ = 0.014 & NOEC < 0.01 g ae/ha Wheat EC ₂₅ = 23.5 & NOEC = 8.8 g ae/ha
123-1(b)	Vegetative Vigor - Tier 2	412965-01	5/25/93	core for veg. vigor test of potassium alt only	0.2885	1989	Soybean EC ₂₅ = 04 & NOEC = 0.125 g ae/ha Wheat EC ₂₅ = 310 & NOEC = 70 g ae/ha

(5) Adequacy of Toxicity Data

Based on Picloram's extreme phytotoxicity, its persistence under typical environmental conditions, and its extreme propensity to leach into ground water in all soil types the

following additional data are needed as confirmatory data to support this risk assessment.

Picloram TIPA Salt
P.C. Code: 005102

Guideline #	Study	Reason Requesting
123-1(a)	Seed Germination/Seedling Emergence - Tier 2	Need missing EC ₂₅ s and NOECs ¹ for most sensitive plants
123-1(b)	Vegetative Vigor - Tier 2	Need missing EC ₂₅ s and NOECs for most sensitive plants
123-1(a)	Seed Germination/Seedling Emergence - Tier 2	Need EC ₂₅ s and NOECs for sensitive crops which were reported in damages from incident reports. These crops include potatoes, tobacco, pasture, watermelons, tomatoes, bell peppers, and hay
123-1(b)	Vegetative Vigor - Tier 2	Need EC ₂₅ s and NOECs for sensitive crops which were reported in damages from incident reports. These crops include potatoes, tobacco, pasture, watermelons, tomatoes, bell peppers, and hay
123-2	Growth & Reproduction of Aquatic Plants - Tier 2	Due to extreme phytotoxicity, ROWs, aerial treatments, etc. all aquatic plant species must to tested. These include <u>Lemna gibba</u> , <u>Skeletonema costatum</u> , <u>Anabaena flos-aquae</u> , & a freshwater diatom.
72-3(d)	Toxicity to Marine/Estuarine Fish LC ₅₀ (TEP)	This study is a minimum core requirement for all active ingredients

will be submitted

¹. The EEB is considering lifting the NOEC requirement.

Guideline #	Study	Reason Requesting
72-4(a)	Early Life Stage - Fish	This pesticide is highly persistent and likely to be present in water on a recurrent basis.

Picloram IOE

P.C. Code: 005103

Guideline #	Study	Reason Requesting
123-1(a)	Seed Germination/Seedling Emergence - Tier 2	Need missing NOEC for most sensitive plants
123-1(b)	Vegetative Vigor - Tier 2	Need missing NOEC for most sensitive plants
123-1(a)	Seed Germination/Seedling Emergence - Tier 2	Need EC ₂₅ s and NOECs for sensitive crops which were reported in damages from incident reports. These crops include potatoes, tobacco, pasture, watermelons, tomatoes, bell peppers, and hay
123-1(b)	Vegetative Vigor - Tier 2	Need EC ₂₅ s and NOECs for sensitive crops which were reported in damages from incident reports. These crops include potatoes, tobacco, pasture, watermelons, tomatoes, bell peppers, and hay
123-2	Growth & Reproduction of Aquatic Plants - Tier 2	Due to extreme phytotoxicity, ROWs, aerial treatments, etc. all aquatic plant species must to tested. These include <u>Lemna gibba</u> , <u>Skeletonema costatum</u> , <u>Anabaena flos-aquae</u> , & a freshwater diatom.
72-1(b)	Bluegill, Acute LC ₅₀ (TEP)	This study is a minimum core requirement for all active ingredients

Guideline #	Study	Reason Requesting
72-1(d)	Rainbow, Acute LC ₅₀ (TEP)	This study is a minimum core requirement for all active ingredients
72-2(b)	Toxicity to Freshwater Invertebrates (<u>Daphnia magna</u>) (TEP)	This study is a minimum core requirement for all active ingredients
72-3(d)	Toxicity to Marine/Estuarine Fish LC ₅₀ (TEP)	This study is a minimum core requirement for all active ingredients
72-3(e)	Toxicity to Marine/Estuarine Mollusc EC ₅₀ (TEP)	This study is a minimum core requirement for all active ingredients
72-3(f)	Toxicity to Marine/Estuarine Shrimp EC ₅₀ (TEP)	This study is a minimum core requirement for all active ingredients
72-4(a)	Early Life Stage - Fish	This pesticide is highly persistent and likely to be present in water on a recurrent basis.

Picloram Potassium Salt
P.C. Code: 005104

Guideline #	Study	Reason Requesting
123-1(a)	Seed Germination/Seedling Emergence - Tier 2	Need missing EC ₂₅ s and NOEC for most sensitive plants
123-1(a)	Seed Germination/Seedling Emergence - Tier 2	Need EC ₂₅ s and NOECs for sensitive crops which were reported in damages from incident reports. These crops include potatoes, tobacco, pasture, watermelons, tomatoes, bell peppers, and hay

Guideline #	Study	Reason Requesting
123-1(b)	Vegetative Vigor - Tier 2	Need EC ₂₅ s and NOECs for sensitive crops which were reported in damages from incident reports. These crops include potatoes, tobacco, pasture, watermelons, tomatoes, bell peppers, and hay
123-2	Growth & Reproduction of Aquatic Plants - Tier 2	Due to extreme phytotoxicity, ROWs, aerial treatments, etc. all aquatic plant species must to tested. These include <u>Lemna gibba</u> , <u>Skeletonema costatum</u> , <u>Anabaena flos-aquae</u> , & a freshwater diatom.
72-3(d)	Toxicity to Marine/Estuarine Fish LC ₅₀ (TEP)	This study is a minimum core requirement for all active ingredients

b. Ecological Effects Risk Assessment

The EFED's principal index of ecological risk (a Risk Quotient or RQ) is computed as a measure of exposure (the EEC) divided by an exposure level of concern (LOC) (USEPA, 1986; 540/9-85-001). The EEC (estimated environmental concentration) is an environmental exposure that can be reasonably anticipated on occasion when the pesticide is used in a normal manner according to label restrictions, computed in accordance with a standardized scenario, as described in greater detail in Section (1) below. The level of concern is a concentration at which the probability of adverse effects is held to be substantial, usually a concentration that has been shown to result in a specified adverse effect in a laboratory bioassay, or a fraction of such a concentration. The criterion for a presumption of low risk is a risk quotient less than one, i.e. estimated exposure concentrations not exceeding exposure levels of concern. Reporting the actual magnitude of the risk quotient (and not just whether or not $RQ > 1$) may assist professional judgement regarding ecological risk, for example when (as for picloram), estimated exposures represent many-fold exceedance of concern levels.

Details of the computation of levels of concern are presented in the sequel in sections devoted to specific categories of nontarget organisms. The toxicity measure is most often an EC_p or some variant (effective concentration for p% response, e.g. EC₅₀ for 50% response). Depending on the type of biological response measured, an EC_p may be the concentration corresponding to a p% change in mean response (e.g. p% reduction in mean weight), or the concentration corresponding to p% of organisms responding (usually p% mortality). In some cases, the toxicity measurement is a low-effect level (LEL), i.e. the lowest dose that resulted in a recognizable effect in a laboratory experiment. Standard exposure scenarios for ecological risk involve transport by runoff or drift of chemical applied to a target plot, to adjacent land or water. Specific details of exposure scenarios are presented in (2) below.

The following important limitations of the standard exposure scenarios are noted here.

- a. For picloram active ingredients, risk calculations are based on a single assumed application, because, as indicated in the Use Profile Section, labels for the most part do not specify maximum annual rates.
- b. The standard exposure scenarios do not address the potential of picloram to contact nontarget plants as a result of irrigation with contaminated surface or ground water. Further consideration of these issues would be necessary in order for the chemical to be eligible for reregistration.

The principal findings and data gaps of the EFED's quantitative risk assessment are summarized as follows, by category of nontarget organism.

Terrestrial Plants. Risks to nontarget terrestrial plants are very significant (endangered species and otherwise) for all active ingredients and all application methods considered. The following table of risk quotients represents the most significant results of the EFED's quantitative risk assessment. For these quotient values, the toxicity measure is the LC₂₅ for

soybean seedling emergence, which is the concentration that causes a quarter of seedlings to fail to emerge. The EEC values used in these computations represents exposure to nontarget plants in areas adjacent to the areas of application, with standard assumptions regarding drift or runoff (Section below on Calculation of EECs).

Number of Times the Level of Concern (LOC) is Exceeded by the
Estimated Environmental Concentration (EEC)^a
(Based on Terrestrial Plants)

Active Ingredient	Application Method		
	Unincorporated Ground	Aerial/ Soil	Aerial/ Foliar
TIPA Salt	4600 ×	7500 ×	550 ×
IOE ^b	5700 ×	-	-
Potassium Salt	8100 ×	13000 ×	280 ×

^a For example (row 1 column 2) the EEC for TIPA salt administered to the ground without incorporation is 4600 times a concentration level of concern.

^b With current registered products, IOE is applied only using backpack sprayers.

For example, a quotient of 4600 is obtained for TIPA administered by ground application without incorporation. This means that *estimated concentrations in the environment are 4600 times a magnitude that, in the laboratory context, causes 25% of soybean seedlings to fail to emerge.* (The "×" symbol is used in the table to emphasize this interpretation.) Soybean seedling emergence was chosen for this calculation because, in keeping with standard practice, it has the smallest of available EC25 measurements (greatest apparent sensitivity) among the measurement endpoints available, representing four different terrestrial plant response variables. The other response variables considered also had quotients mostly greater than one, indicating substantial risk.

Based on reports of incidents involving damage to crops, a complete risk assessment

would require additional phytotoxicity data for various crops including potatoes, tobacco, soybeans, corn, watermelons, tomatoes, bell peppers, hay, and pasture.

Aquatic Organisms (Plants and Animals). *Data requirements are not fulfilled for aquatic plants or for aquatic animals.* There are currently no registered aquatic uses of picloram; however, again, picloram is exceptionally mobile and persistent, and therefore has exceptional potential for exposure of aquatic organisms, relative to other pesticides with terrestrial uses only. Also, picloram has been shown to be very toxic to terrestrial plants, for which the database is more complete than for aquatic plants.

For aquatic animals, estimated exposures exceed levels of concern for endangered fish species, for potassium salt administered by ground application without incorporation. A complete risk assessment for aquatic animals would require the following acute toxicity studies which have not been submitted: For IOE, no aquatic toxicity studies are available. The minimal set of additional studies would comprise coldwater fish (rainbow trout), warmwater fish (bluegill), freshwater invertebrate, and marine invertebrate. For potassium and TIPA salts, a marine fish study would be required. In addition a fish early life cycle study would be required for TIPA salt and IOE. Availability of complete toxicity data would likely result in identification of additional concerns for aquatic animals, because exposures approach levels of concern for various combinations of species, chemical and application method.

For aquatic plants, only one species has been tested (*Selenastrum carpricornutum*), of the five that are normally required. The *Selenastrum* data did not indicate a concern. The *additional studies would have substantial informational value in view of the high mobility, persistence, and phytotoxicity of the chemicals.* The aquatic vascular plant study (*Lemna sp.*) could be particularly important, because of the demonstrated high toxicity to several terrestrial vascular species.

Given the low octanol-water partition coefficient, significant *bioaccumulation* in aquatic organisms is not anticipated.

Terrestrial birds and mammals. *For mammals, exposure to endangered terrestrial species will likely exceed levels of concern for TIPA and potassium salts, administered by all application methods considered.* For non-endangered species, exposures were not found to exceed levels of concern.

For birds (endangered and non-endangered), exposures were not found to exceed levels of concern based on acute or chronic toxicity.

No further avian or mammalian toxicity studies will be required at this time.

Mitigation and Labelling. For terrestrial plants, use rates that would result in estimated environmental concentrations below levels of concern vary by application procedure and

product, but are uniformly lower than 1% of current label rates.

Registration would require label rate restrictions beyond those available for most picloram products, as discussed further in Section 3 (Labelling Requirements).

Section (1) below (Calculation of EECs) reviews procedures for translating use rates into estimates of concentrations encountered in the environment by nontarget organisms. Subsequent sections present quantitative risk assessments for specific categories of nontarget organisms.

(1) Calculation of Estimated Environmental Concentrations

EEC calculations are based on maximum use rates identified in the previous section (2.2 lb ai/A for TIPA salt; 2 lb ai/A for IOE and Potassium salt), along with additional assumptions regarding transport, dilution, and concentration. As indicated, *results are based on a single application*. This section describes the procedures used by EFED for calculating EECs: the numerical results are presented in sections devoted to specific categories of nontarget organisms.

Nontarget Terrestrial vertebrates, dietary exposure. EEC values for assessment of risk to terrestrial vertebrates are based on the procedure of Kenaga and Hoerger, as described in the ecological risk Standard Evaluation Procedure (USEPA, 1986; 540/9-85-001). Results are *illustrated for TIPA salt*: Corresponding to a single application of TIPA salt at 2.2 lb ai/A, the dietary EECs based on the method of Kenaga and Hoerger are given by wildlife use site as follows.

<u>Use Sites</u>	<u>Residues (ppm)</u> (TIPA salt)
Range grasses (short)	528
Long grasses	242
Leaves and leafy crops	275
Forage crops (small insects)	128
Pods containing seeds (large insects)	26
Fruits	15
Soil (Top 1 inch)	49

Corresponding to an application of TIPA salt at 2.2 lb ai/A, the EEC is the maximum value (528 ppm), based on short range grasses. For an application of IOE or potassium salt applied at 2 lb ai/A the EEC is 480 ppm ($=528 \times 2/2.2$).

Nontarget Terrestrial Plants. EEC values are based on the assumption that chemical applied

to a target plot is transported by drift and/or runoff (depending on the application method), to an adjacent "nontarget" plot, of area equal to that of the target plot, where it is distributed evenly. Application methods, considered separately for picloram active ingredients, are unincorporated ground application, and aerial application (foliar and soil).

- For unincorporated ground applications exposure to nontarget organisms is assumed to result from runoff. The fraction of chemical applied that is transported to the nontarget plot is based on water solubility as follows:

<u>Water Solubility (ppm)</u>	<u>% Runoff</u>
< 0.001	0.1
0.001 to 10	1
10 to 100	2
> 100	5

Therefore, it is assumed that 5% of chemical applied is transported by runoff for TIPA salt and potassium salt, 1% for IOE. Total mass transported by runoff (per application) is therefore as follows:

<u>Active Ingredient</u>	<u>EEC</u>	<u>(%Runoff × Appl. Rate)</u>
TIPA salt	0.11 lb ai/A	(=2.2 × 0.05),
IOE	0.02 lb ai/A	(=2.0 × 0.01),
Potassium salt	0.10 lb ai/A	(=2.0 × 0.05).

However, IOE is expected to degrade rapidly to forms with high water solubility (over 100 ppm). For IOE, substitution of a 5% runoff assumption would multiply by 5 various risk quotients presented in the sequel.

- For aerial application to soil it is assumed that the chemical is transported by *both runoff and drift*, and the EEC is calculated as the sum of terms representing these two transport mechanisms.

$$\text{EEC (lb/A)} = \text{Runoff (lb/A)} + \text{Drift (lb/A)}$$

It is assumed that the nontarget plot receives 5% of the chemical administered to the nontarget plot, *by drift*. The quantity transported *by runoff* is given by

$$\text{Maximum Appl. Rate (lb/A)} \times 60\% \text{ Efficiency} \times \% \text{Runoff}$$

Percentage runoff is calculated based on water solubility in the same way as just described for unincorporated ground application.

- For aerial application to foliage, it is assumed that the nontarget plot receives 5% of the quantity applied on the target plot, by drift.

Nontarget Aquatic Organisms (Plants and Animals). It is assumed that a fraction of chemical applied to a 10-acre plot is transported by drift and/or runoff to a body with surface area one acre and depth 6 feet ("deep" water body) or 6 inches ("shallow" water body). *Identification of risk levels of concern is based on the shallow water body scenario (6 inch depth) for endangered species, and on the deep water body scenario (6 feet depth) for non-endangered species.*

- For unincorporated ground applications, it is assumed that *transport is by runoff*. The fraction of material transported from a 10-acre catchment is estimated based on solubility, as for terrestrial plant exposures (5% for TIPA salt and potassium salt, 1% for IOE). It is assumed that all of the runoff from the 10-acre catchment is intercepted by the 1-acre water body. The mass loading for the receiving water body (w.b.) is therefore given by

$$\begin{array}{l} \text{Mass Loading} \\ (\text{lb./A w.b.}) \end{array} = \begin{array}{l} \text{Maximum} \\ (\text{lb./A catchment}) \end{array} \times \begin{array}{l} \% \text{ Runoff} \\ / \text{ A surface} \end{array} \times 10 \text{ A catchment}$$

Conversion of the mass loading to an EEC (in ppb), is based on the assumed depth of the water body. For the deeper water body the EEC is obtained by multiplying the mass loading by 61.2 (≈ 61) ppb/(lb./A). For the more shallow water body the same mass will be concentrated in a volume one twelfth of the volume of the deeper water body, so the conversion factor is 734 ppb/(lb.A) ($=61.2 \times 12$).

For example, the EEC for TIPA salt in the deeper water body is

$$67 \text{ ppb} = 2.2 \times 0.05 \times 10 \times 61.$$

- For aerial applications (not assessed separately for soil and foliage), transport is by *both runoff and drift*, and the resulting EEC is the sum of terms representing these two transport mechanisms. For *runoff*, it is assumed that 60% of the material applied is susceptible to runoff (60% is the "application efficiency"). Of that fraction, the assumed percentage runoff is based on water solubility as described for nontarget terrestrial plants (5% for TIPA salt and potassium salt, 1% for IOE). All of the runoff from a 10-acre catchment is received by a 1-acre water body. Accordingly the mass loading resulting from runoff is given by

$$\text{Mass Loading (lb./A w.b.)} = \frac{\text{Maximum Appl. (lb./A catchment)} \times 60\% \text{ Efficiency} \times 10 \text{ A catchment} \times \% \text{Runoff}}{\text{A surface}}$$

For input by *drift*, it is assumed that the water body receives 5% of the quantity applied to an adjacent equal-area plot. Finally, the total mass loading (representing drift plus runoff) is converted to an EEC (in ppb) by the procedure just described for unincorporated ground applications. (Multiply by 61 for the deeper water body or by 734 for the more shallow water body.)

(3) Non-target Terrestrial Vertebrates

i. Avian Acute Risk

For avian acute risk, exposure levels of concern are LC50/2 for non-endangered species and LC50/10 for endangered species. Calculation of the EEC representing dietary exposure is based on maximum application rates identified in the Use Profile Section (repeated in tables following), using procedures described in Section (1), for nontarget terrestrial vertebrates.

Additional calculations that are standard for granular pesticide formulations, involving numbers of LD₅₀s per square feet, are not applicable to products containing picloram salts and IOE.

Endangered Bird Species. As indicated in the following table, the estimated exposure levels do not exceed levels of concern.

Acute Avian Dietary Risk for <i>Endangered Species</i> ¹			
Active Ingredient	Dietary LC ₅₀ (ppm)	Highest Calculated EEC (ppm)	Risk Quotient (RQ) EEC/(LC50/10)
TIPA Salt	> 10000	528	< 0.528
IOE	> 5620	480	< 0.854
Potassium Salt	> 5620	480	< 0.854

¹ Non-endangered species: RQ values are values given for endangered species, divided by 5. (All RQ < 1.)

Non-Endangered Bird Species. Estimated exposures do not exceed levels of concern for non-endangered bird species. Risk assessment for non-endangered species is similar to that for endangered species (just described), except that levels of concern are calculated as LC50/2 rather than LC50/10. It follows that for nonendangered species, the RQ values are <0.11 for TIPA salt, <0.17 for IOE and Potassium salt.

ii. Avian Chronic Risk

For avian chronic risk, estimated exposures do not exceed levels of concern. Levels of concern are lowest effect levels (LEL). Supplemental studies conducted more than 10 years ago give NOELs 2.8 kg ai/ha (15.2 lb ai/A) for TIPA salt and 11.2 kg ai/ha (60.9 lb ai/A) for Potassium salt. (NOEL="No Observed Effect Level" <LEL). By the method of Kenaga and Hoerger, the EEC corresponding to 15.2 lb ai/A NOEL is 3648 ppm (=15.2 lb ai × 240 ppm/lb ai). This is substantially larger than the previously-computed EEC of 528 (corresponding to the maximum label use rate of 2.2 lb ai/A). In short, the actual environmental concentration is estimated to be much lower than a value that produced no discernable effect.

iii. Mammalian Acute Risk

Quantitative risk assessment for mammals is similar to that for birds, but requires, in addition, conversion of LD50 values (mg ai per kg body weight) to LC50 values in the same units as the EECs (ppm). Exposure levels of concern are calculated as LC50/2 for non-endangered species and LC50/10 for endangered species. Calculation of the EEC representing dietary exposure is based on maximum application rates identified in Section (1) (repeated in tables following), using procedures described in Section (2) for nontarget terrestrial vertebrates.

Conversion of LD50s to LC50s is represented by the following formula.

$$LC50 = \frac{LD50 \text{ (mg/kg)} \times \text{Body Weight (gms)}}{\text{Weight Consumed (gms)}}$$

Assumptions regarding body weight and food consumption are here based on Davis and Golly (1963).

The RQ calculations for an endangered mammal are illustrated in the following table, for picloram TIPA salt. LC50s are for three species that are representative of small wild mammals. The lowest relevant LD50 measurement was more than 5000 mg/kg:

**Risk Quotient Calculation Illustrated for a Hypothetical Endangered Mammal with LC50
5000 mg/kg, Based on
picloram TIPA salt**

Species	Body Weight (gms)	Daily Food Intake		LC50 (ppm) ¹	Risk Quotient (RQ) ²
		% Body Weight	grams		
Meadow vole (herbivore)	46	61	28.1	8185	0.645
Old-field mouse (granivore)	13	16	2.1	30952	0.17
Least shrew (Insectivore)	5	110	5.5	4545	1.16

¹ Based on LD50 = 5000 mg/kg.
² RQ = EEC / (0.1 × LC50);
 EEC = 528 ppm
 Non-Endangered: use RQ = EEC / (0.5 × LC50)

Acute Risk to Endangered Mammalian Species. Risk quotients computed as just described are presented in the following table. These results indicate exceedance of exposure levels of concern for acute risk, for endangered insectivores from exposure to picloram TIPA and Potassium salts, and for mammalian herbivores exposed to IOE.

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Acute Risk Quotients for Endangered Mammals

Active Ingredient (P.C Code)	Mammal LC50 (ppm)	Highest Calculated EEC Value (ppm)	Risk Quotient (EEC/ (0.1×LC50))
TIPA Salt (5102) LD₅₀ > 5000 mg/kg	8185 Meadow vole (herbivore) 30952 Old field mouse (granivore) 4545 Least shrew (insectivore)	528	0.645 0.17 1.16
IOE (5103) LD₅₀ = 2830 mg/kg	4632 Meadow vole (herbivore) 17519 Old field mouse (granivore) 2572.7 Least shrew (insectivore)	480	1.036 0.274 1.866
Potassium Salt (5104) LD₅₀ = 3536 mg/kg	5788.5 Meadow vole (herbivore) 21889.5 Old field mouse (granivore) 3214.6 Least shrew (insectivore)	480	0.829 0.219 1.5

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Acute Risk to Nonendangered Mammal Species. Estimated exposures do not exceed levels of concern for nonendangered mammals. Levels of concern are calculated as LC50/2, rather than LC50/10 as for endangered mammals. Therefore RQ values for nonendangered mammals are equal to the values displayed above for endangered mammals, divided by 5. The maximum RQ value for nonendangered mammals is therefore 0.37 (=1.866/5), corresponding to IOE and least shrew.

iv. Mammalian Chronic Risk

Because risks are low for acute effects, as just described, the EFED has not requested chronic toxicity studies. For both endangered and non-endangered mammal species, levels of concern for chronic effects are lowest effect levels (LEL).

(4) Non-target Terrestrial Plants

For non-target terrestrial plants (endangered or nonendangered), exposure levels of concern are equated to the lowest relevant EC25 measurements. Risk is assessed by application method: unincorporated ground, aerial to soil, or aerial to foliar. Calculation of EECs is based on maximum application rates identified Section (1), repeated in subsequent tables.

Unincorporated Ground Application. The following table gives risk quotients for each active ingredient, along with the application rates that would yield RQ=1. As described previously, EECs are based on the assumption that chemical applied to a target plot is transported by runoff to an adjacent nontarget plot, with the assumed percentage runoff based on water solubility. The results displayed below indicate that *picloram salts and IOE are very likely to affect nontarget plants (especially dicots) in areas adjacent to areas of application. The requirement for Tier 3 plant field testing has been met; however, current EPA policy does not require these studies.*

Terrestrial Plants Exposed via Runoff, Unincorporated Ground Application (Endangered or Non-endangered)					
Active Ingredient (P.C Code)	Seed Germination EC ₂₅ Seedling Emergence LC ₂₅ (lb ai/A)	Maximum Application Rate (lb ai/A)	% Runoff Based on Solubility	EEC (lb ai/A)	Risk Quotient (EEC/EC ₂₅)
TIPA Salt (5102)	0.002 (Dicots-Soybeans) > 0.035 (Monocots-barley)	2.2	5	0.11	55
					< 3.14
	0.0000239 (Dicots-Soybeans) 0.0346 (Monocots-wheat)				4603 3.18
IOE (5103)	0.0013376 (Dicots-Drybeans) 0.0032103 (Monocots-barley)	2.0	1	0.02	14.99
					6.23
	3.5 × 10 ⁶ (Dicots-Soybeans) 0.0253259 (Monocots-wheat)				5714 0.790
Potassium Salt (5104)	0.0031 (Dicots-Soybeans) 0.062 (Monocots-Barley)	2.0	5	0.1	32.3
					1.61
	0.0000124 (Dicots-Soybeans) 0.02 (Monocots-Wheat)				8065 5

Aerial Application to Soil. As described previously, EECs are based on the assumption that chemical applied to a target plot is transported by both drift and runoff to an adjacent nontarget plot of equal area. Results of these calculations (displayed in the following table) indicate that picloram salts pose significant risks to nontarget plants (especially dicots) in areas adjacent to application plots, when the chemical is applied aerially to soil. The requirement for Tier 3 plant field testing is met; however, current EPA policy does not require these studies. The same result is obtained for IOE; however IOE is currently applied only using backpack sprayers.

Risks to Nontarget Terrestrial Plants (Endangered, Non-Endangered), Aerial/Soil Application					
Active Ingredient (P.C Code)	Seed Germination EC ₂₅ Seedling Emergence LC ₂₅ (lb ai/A)	Maximum Application Rate (lb ai/A)	% Runoff Based on Solubility	EEC (lb ai/A)	Risk Quotient (EEC/EC ₂₅)
TIPA Salt (5102)	0.002 (Dicots-Soybeans)	2.2	5	0.18	90
	0.035 (Monocots-barley)				5.1
	0.0000239 (Dicots-Soybeans)				7531
	0.062 (Monocots-wheat)				2.9
IOE (5103)	0.0013376 (Dicots-Drybeans)	2.0	1	0.032	23.9
	0.0032103 (Monocots-barley)				9.9679
	3.5 × 10 ⁻⁴ (Dicots-Soybeans)				9143
	0.0253259 (Monocots-wheat)				1.2635
Potassium Salt (5104)	0.0031 (Dicots-Soybeans)	2.0	5	0.16	51.6
	0.062 (Monocots-Barley)				2.5
	0.0000124 (Dicots-Soybeans)				12,903
	0.02 (Monocots-Wheat)				8

Aerial Application - Foliar. As described previously, EECs are calculated under the assumption that 5% of the chemical applied to a nontarget plot is transported by runoff to an adjacent nontarget plot of equal area. The resulting risk quotient values (displayed in the following table) indicate that *picloram salts pose significant risks to nontarget dicot plants and root crops in areas adjacent to application areas* when the chemical is applied by foliar aerial applications. The same result is obtained for IOE; however IOE is currently applied only using backpack sprayers. *The requirement for Tier 3 plant field testing is met; however, current EPA policy does not require these studies.*

Risk to Nontarget Terrestrial Plants (Endangered, Non-endangered) from Aerial Foliar Application.					
Active Ingredient (P.C Code)	Vegetative Vigor EC ₂₅ (lb ai/A)	Maximum Application Rate (lb ai/A)	% Runoff Based on Drift	EEC (lb ai/A)	Risk Quotient (EEC/EC ₂₅)
TIPA Salt (5102)	0.0002 (Dicots-Tomatoes)	2.2	5	0.11	550
	0.20 (Monocots-Wheat)				0.55
	0.012 (Root crops-Radish)				9.2
IOE (5103)	0.000214 (Dicots-Soybeans)	2.0	1	0.02	93.
	0.2098307 (Monocots-Wheat)				0.095
	0.0346893 (Root crops-Radish)				0.58
Potassium Salt (5104)	0.00036 (Dicots-Soybeans)	2.0	5	0.1	277.7
	0.276 (Monocots-Wheat)				0.36
	0.062 (Root crops-Radish)				1.6

Additional Phytotoxicity Information. There are a substantial number of reports of incidents in which products containing picloram active ingredients have been claimed to damage crops. The Agency regards damage to crops by picloram as highly plausible, however the scientific merit of the specific reports has not been completely investigated in the Agency. Further evaluation of these reports would be needed in order for the chemical to be eligible for registration; in particular, the requirement of *phytotoxicity data for potatoes and other sensitive crops would be indicated* in that case.

Additionally, a study of use of picloram in the northern Rocky Mountains, to control noxious weeds along logging roads, concluded that roadside applications should not exceed 0.25 lb ai/A, and that less than 1% of a given watershed should be treated (Watson et al. 1989). Currently, none of the Picloram labels address the maximum watershed area that can be treated per year.

(5) Non-target Aquatic Plants

For nontarget aquatic plants, a complete risk assessment involves toxicity tests for five plant species. At present data are available only for *Selenastrum capricornutum* (a freshwater green alga).

Standard quantitative risk calculations have been performed based on the *S. capricornutum* toxicity measurements. This incomplete risk assessment, which is not

presented here in detail, indicates that exposure levels of concern are not exceeded for picloram salts and IOE. This result does not indicate that current picloram uses are benign for nontarget aquatic plants in general: testing of the additional species would be required as confirmatory data to justify such a presumption, particularly for a herbicide.

(6) Non-target Aquatic Animals

i. Acute Risks

Acute risk to non-target aquatic animals is presumed low for risk quotient (RQ) values less than 1, calculating RQ as $EEC/(0.1 \times LC50)$ (nonendangered species) or $EEC/(0.05 \times LC50)$ (endangered species), based on the lowest relevant LC50 measurement. The calculation of EECs depends upon the maximum use rates identified in the Use Profile Section and formulae given in Section (1). EEC calculations assume that a proportion of chemical applied in a 10 acre drainage basin is transported by drift and/or runoff (depending on the application method) to a 1 acre water body, depth 6 feet or 6 inches. Again, concentration levels of concern are based on the 6 inch depth for endangered species and on 6 foot depth for non-endangered species.

A reasonably complete acute risk assessment would require, at minimum, the following acute toxicity studies not presently available: for TIPA salt and IOE, LC50s for a coldwater fish (rainbow trout), a warmwater fish (bluegill), and a freshwater invertebrate (Daphnia magna); for potassium salt the LC50 for bluegill. For IOE, there are no available acute toxicity data for freshwater marine/estuarine organisms.

Standard calculations have been performed using the available toxicity data. The results are presented in detail only for endangered species, for which in some cases the risk quotients approach or exceed one. For non-endangered species, risk quotients can be obtained as 0.5 times the values presented for endangered species. This incomplete risk assessment has identified the following ecological risk concern: *The potassium salt is likely to effect endangered fish with unincorporated ground application (risk quotient=1.13).* With plausible levels of variation in sensitivity among species, it is not improbable that additional concerns would be identified if the minimal toxicity data requirements identified were fulfilled. An additional risk quotient greater than one is obtained with the endangered species risk assessment for TIPA salt, based on the eastern oyster shell deposition test (unincorporated ground application); however, currently there are no federally listed marine or estuarine organisms.

In 1989, 15880 pounds of fish died with symptoms of chemical poisoning in a hatchery in Sheridan Montana. Picloram (Tordon 22K) was reportedly detected at the site, and the chemical had been sprayed one quarter mile upstream from the hatchery by Montana State Highway personnel. In order for the chemical to be eligible for registration, further evaluation of the scientific merit of the incident would be warranted within the Agency.

Unincorporated Ground Applications, Endangered Species. As described previously for

aquatic organisms (plants and animals) EEC calculations assume that chemical applied to a target plot is transported by runoff to an adjacent plot of equal area, at a rate that depends on water solubility of the chemical. Results are presented separately for TIPA salt and potassium salt in the following tables. (*For IOE there are no available aquatic toxicity data.*) For TIPA and potassium salt, it is assumed that 5% of chemical applied is transported to the nontarget plot, based on the high water solubility of these chemicals.

For *nonendangered species*, risk quotients will equal 0.5 times the values presented.

**Risk Quotients (RQ) for Endangered Aquatic Animals,
based on Unincorporated Ground Applications**

1. **Picloram TIPA salt Applied at 2.2 lb. ai/A**

Species	LC ₅₀ (ppb)	RQ 6 Feet Deep (67.1/(0.05 x LC ₅₀))	RQ 6 Inch Deep (807.4/(0.05 x LC ₅₀))
Coho Salmon (FW fish - coldwater)	20,000	0.067	0.807
Marine Shrimp	306,000	0.0044	0.0528
Eastern Oyster (Shell deposition)	10,000	0.134	1.615

2. **Picloram IOE: no toxicity data.**

3. **Picloram Potassium Salt Applied at 2.0 lb. ai/A**

Species	LC ₅₀ (ppb)	RQ 6 Feet Deep (61/(0.05 x LC ₅₀))	RQ 6 Inch Shallows (734/(0.05 x LC ₅₀))
Rainbow Trout (FW fish - coldwater)	13,000	0.0938	1.13
Daphnia (FW Invertebrate)	68,300	0.0179	0.215
Eastern Oyster (Embryo Larvae)	18,000	0.0677	0.816

Aerial or Mist Blower Applications (endangered species). EECs are calculated as described in Section (1) for aquatic organisms (both animals and plants), under the assumption that a water body with 1 acre surface receives input of chemical by both drift and runoff from the 10-acre plot.

Results are presented separately for TIPA salt and potassium salt in the following tables. (For IOE there are no available aquatic toxicity data.) For nonendangered species, risk quotients will equal 0.5 times the values presented.

**Risk Quotients (RQ) for Endangered Aquatic Animals
based on Aerial Application**

- 1. Picloram TIPA Salt Applied at 2.2 lb. ai/A

Species	LC ₅₀ ppb	RQ 6 Feet Deep (47/(0.1 x LC ₅₀))	RQ 6 Inch Shallows (566/(0.1 x LC ₅₀))
Coho Salmon (FW fish - coldwater)	20,000	0.0235	0.283
Marine Shrimp	306,000	0.00154	0.0185
Eastern Oyster (Shell deposition)	10,000	0.047	0.566

2. Picloram IOE: No toxicity data.

3. Picloram Potassium Salt Applied of 2.0 lb. ai/A

SPECIES	LC ₅₀ ppb	RQ 6 FEET DEEP (42.7/(0.1 x LC ₅₀))	RQ 6 INCH SHALLOWS (514.5/(0.1 x LC ₅₀))
Rainbow Trout (FW fish - coldwater)	13,000	0.0323	0.396
Daphnia (FW Invertebrate)	68,300	0.00625	0.0753
Eastern Oyster (Embryo Larvae)	18,000	0.0237	0.2858

ii. Chronic Risk to Aquatic Animals

Subdivision E, Section 72-4 of FIFRA requires submission of a fish early life-cycle test for pesticides that are likely to be highly persistent in the aquatic environment. The only picloram active ingredient for which this requirement is satisfied is potassium salt. *Chronic fish studies are needed for the remaining active ingredients.*

For risks of chronic effects, levels of concern are equated to Maximum Acceptable Concentrations (MATC). For the picloram potassium salt, MATCs for the fish early life stage and aquatic invertebrate life-cycle tests are 700 ppb and 14600 ppb respectively. Neither of these values exceeds relevant EECs based on the application methods considered here (unincorporated ground application and aerial application).

(7) Non-target Insects

As indicated in discussion of toxicity data, honey bee acute toxicity studies indicate that

all active ingredients of picloram are *practically nontoxic to that species*, with contact LD50 > 25 mg per bee.

3. Labelling Requirements and Potential Mitigation

Contamination of surface and ground water cannot be effectively mitigated for picloram products: because of the exceptional persistence and mobility of these chemicals, any further use will result in continued accumulation in ground water.

As an indication of potential for mitigation of ecological effects *by use reduction*, one can estimate the maximum use rate that would correspond to an environmental concentration not exceeding the level of concern. The reciprocal of the risk quotients (i.e. 1/RQ) gives the *fraction* of the current use rate that would result in an EEC equal to the LOC. For example, if the risk quotient is 2, then a halving of the application rate would result in an EEC equal to the LOC. Results of such calculations, based on RQ values in tables above, vary according to product and application procedure, but uniformly indicate that application rates less than 1% of current rates would be required, for the EECs to not exceed the LOCs.

As stated above in the Use Profile section there are many labelling issues which are not addressed. These issues mainly concern maximum rates per application, per year or season, and the intervals between applications. These issues are summarized below by active ingredient.

Picloram TIPA Salt
P.C. Code: 005102

These products can be applied at any season and there are no limitations or restrictions on the maximum number of treatments per season. The maximum rates per application are also unclear. For the tree injection method 1 ml of undiluted product is injected at intervals of 2 - 3 inches between the edges of injector wounds, however, it is not specified if 1 ml is injected at each interval or whether a total of 1 ml of product is injected per tree. EFED asked DowElanco to clarify these issues, and were sent clarification in the form of a fax (attached). DowElanco responded that 1 milliliter is injected into each injection wound at an average of 5 injections per tree. The maximum plant density was considered to be 500 stems per acre, and the maximum poundage per acre was calculated to be 0.1 68 lb ai/A. Applications are "typically" applied once every 3 to 4 years. The maximum rate used in the risk assessment was, therefore, 2 lb ai/A from the broadcast stubble treatment.

Picloram IOE
P.C. Code: 005103

The only product containing this active ingredient is applied as a basal bark treatment by backpack sprayer. There are no limitations on the maximum number of treatments or intervals between treatments. It can be diluted as 2 gallons (908 g ae) of product in enough

oil to make 100 gallons of spray mixture and applied with a backpack sprayer using low pressure (20 to 40 psi) at the spray nozzle or it can be diluted as 30 gallons (13,620 g ae) of product to make 100 gallons and applied as a low volume treatment using low pressure and a cone or flat fan nozzle. The only apparent difference with these two dilutions is that the low volume treatment does not wet the stem to the point of runoff. Alternatively, Access may be applied undiluted "in a thin stream to all sides of the lower stems". Between 2 to 15 ml (0.0005284 to 0.003969 g ae) is required for treatment of a single stem. As discussed in the Use Profile section above the undiluted treatment of 15 ml yields a maximum application rate of 2 lb ai/A (500 stems x 15 ml)/3785 ml/gallon). Therefore, the maximum rate used in this risk assessment for the IOE is 2.00 lb ai/A. It should also be noted that the EFED is in the process of verification of the vegetation density assumption of 500 stems per acre.

Picloram Potassium Salt
P.C. Code: 005104

Of the three products containing this Picloram salt Tordon K and Tordon 22K does not give limitations on the maximum number of treatments per season. However, it may be inferred that Tordon 22K is applied on time per season. For the EEC calculations for the risk assessment a maximum seasonal rate of 2 lb ai/A per year was used. This issue should be clarified in the labels.

Concerning endangered species, the Endangered Species Protection Program is expected to become final in early 1994. Picloram has existing biological opinions for which EPA will require a generic endangered species label statement (or an equivalently protective alternative) when the program is in place. Additional consultation with the U.S. Fish and Wildlife Service will be required to address newly listed species and also any use sites not previously considered. However, no additional label changes are anticipated as a result of consultation if the label already contains the generic label statement.

Precautionary Label Statement - (Manufacturing Use Product). Labelling standards applied to picloram products would indicate that the following precautionary statement should be included on labels for all products.

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

References 1. MRID Fate and Groundwater Studies

Note: MRID ecological effects studies are not included in the following. The EFED has not at this time established consistency in recording MRID references.

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References 2. Other References

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